UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/576,496 | 04/20/2006 | Toshihisa Komori | Q94468 | 4656 |

23373 7590 05/14/2008

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

| EXAMINER | |
|---|---|
| DUNSTON, JENNIFER ANN | |
| ART UNIT | PAPER NUMBER |
| 1636 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 05/14/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/576,496 | KOMORI ET AL. | |
| | Examiner | Art Unit | |
| | Jennifer Dunston | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-7,9,15-22 and 31-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-7, 9, 15-22 and 31-38* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-7, 9, 15-22 and 31-38 are pending in the instant application.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, drawn to a method for obtaining a disease-associated gene, comprising screening gene expression induced or inhibited by a transcription factor.

Group II, claim(s) 5-7, drawn to a chondrocyte from a Runx2/Cbfa1-deficient mouse.

Group III, claim(s) 9, 15-19 and claim 31 (as it reads on SEQ ID NOs: 9 and 35, drawn to a polynucleotide of SEQ ID NO: 9 or 35, and variants thereof, vectors comprising said polynucleotide, and cells transformed with said vectors.

Group IV, claim(s) 20-22, drawn to a polypeptide comprising SEQ ID NO: 10, or a variant thereof.

Group V, claim(s) 31 (as it reads on SEQ ID NOs: 1 and 27), drawn to a pharmaceutical composition comprising a polynucleotide having 65% or more homology or hybridizing to the nucleotide sequence shown in SEQ ID NO: 1 or 27.

Group VI, claim(s) 31 (as it reads on SEQ ID NOs: 3 and 29), drawn to a pharmaceutical composition comprising a polynucleotide having 65% or more homology or hybridizing to the nucleotide sequence shown in SEQ ID NO: 3 or 29.

Group VII, claim(s) 31 (as it reads on SEQ ID NOs: 5 and 31), drawn to a pharmaceutical composition comprising a polynucleotide having 65% or more homology or hybridizing to the nucleotide sequence shown in SEQ ID NO: 5 or 31.

Group VIII, claim(s) 31 (as it reads on SEQ ID NOs: 15 and 41), drawn to a pharmaceutical composition comprising a polynucleotide having 65% or more homology or hybridizing to the nucleotide sequence shown in SEQ ID NO: 15 or 41.

Group IX, claim(s) 31 (as it reads on SEQ ID NOs: 25 and 51), drawn to a pharmaceutical composition comprising a polynucleotide having 65% or more homology or hybridizing to the nucleotide sequence shown in SEQ ID NO: 1 or 27.

Group X, claim(s) 32-33 (as they read on SEQ ID NOs: 1 and 27), drawn to a method for preventing and/or treating a bone and/or joint disease comprising administering to a subject a polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 1 or 27.

Group XI, claim(s) 32-33 (as they read on SEQ ID NOs: 3 and 29), drawn to a method for preventing and/or treating a bone and/or joint disease comprising administering to a subject a polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 3 or 29.

Group XII, claim(s) 32-33 (as they read on SEQ ID NOs: 5 and 31), drawn to a method for preventing and/or treating a bone and/or joint disease comprising administering to a subject a polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 5 or 31.

Group XIII, claim(s) 32-33 (as they read on SEQ ID NOs: 9 and 35), drawn to a method for preventing and/or treating a bone and/or joint disease comprising administering to a subject a polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 9 or 35.

Group XIV, claim(s) 32-33 (as they read on SEQ ID NOs: 15 and 41), drawn to a method for preventing and/or treating a bone and/or joint disease comprising administering to a subject a polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 15 or 41.

Group XV, claim(s) 32-33 (as they read on SEQ ID NOs: 25 and 51), drawn to a method for preventing and/or treating a bone and/or joint disease comprising administering to a subject a polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 25 or 51.

Group XVI, claim(s) 34-36 (as they read on SEQ ID NOs: 1 and 27), drawn to a method for diagnosing a disease comprising contacting a sample with a polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 1 or 27.

Group XVII, claim(s) 34-36 (as they read on SEQ ID NOs: 3 and 29), drawn to a method for diagnosing a disease comprising contacting a sample with a polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 3 or 29.

Group XVIII, claim(s) 34-36 (as they read on SEQ ID NOs: 5 and 31), drawn to a method for diagnosing a disease comprising contacting a sample with a polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 5 or 31.

Group XIX, claim(s) 34-36 (as they read on SEQ ID NOs: 9 and 35), drawn to a method for diagnosing a disease comprising contacting a sample with a polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 9 or 35.

Group XX, claim(s) 34-36 (as they read on SEQ ID NOs: 15 and 41), drawn to a method for diagnosing a disease comprising contacting a sample with a polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 15 or 41.

Group XXI, claim(s) 34-36 (as they read on SEQ ID NOs: 25 and 51), drawn to a method for diagnosing a disease comprising contacting a sample with a polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 25 or 51.

Group XXII, claim(s) 37 (in part, as it reads on enhanced expression of SEQ ID NOs: 1 and 27) and claim 38, drawn to a transgenic animal model in which an expression level of the gene encoded by the polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 1 or 27 is enhanced.

Group XXIII, claim(s) 37 (in part, as it reads on enhanced expression of SEQ ID NOs: 3 and 29) and claim 38, drawn to a transgenic animal model in which an expression level of the gene encoded by the polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 3 or 29 is enhanced.

Group XXIV, claim(s) 37 (in part, as it reads on enhanced expression of SEQ ID NOs: 5 and 31) and claim 38, drawn to a transgenic animal model in which an expression level of the gene encoded by the polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 5 or 31 is enhanced.

Group XXV, claim(s) 37 (in part, as it reads on enhanced expression of SEQ ID NOs: 9 and 35) and claim 38, drawn to a transgenic animal model in which an expression level of the gene encoded by the polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 9 or 35 is enhanced.

Group XXVI, claim(s) 37 (in part, as it reads on enhanced expression of SEQ ID NOs: 15 and 41) and claim 38, drawn to a transgenic animal model in which an expression level of the gene encoded by the polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 15 or 41 is enhanced.

Group XXVII, claim(s) 37 (in part, as it reads on enhanced expression of SEQ ID NOs: 25 and 51) and claim 38, drawn to a transgenic animal model in which an expression level of the gene encoded by the polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 25 or 51 is enhanced.

Group XXVIII, claim(s) 37 (in part, as it reads on lowered expression of SEQ ID NOs: 1 and 27), drawn to a transgenic animal model in which an expression level of the gene encoded by the polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 1 or 27 is lowered.

Group XXIX, claim(s) 37 (in part, as it reads on lowered expression of SEQ ID NOs: 3 and 29), drawn to a transgenic animal model in which an expression level of the gene encoded by the polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 3 or 29 is lowered.

Group XXX, claim(s) 37 (in part, as it reads on lowered expression of SEQ ID NOs: 5 and 31), drawn to a transgenic animal model in which an expression level of the gene encoded by the polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 5 or 31 is lowered.

Group XXXI, claim(s) 37 (in part, as it reads on lowered expression of SEQ ID NOs: 9 and 35), drawn to a transgenic animal model in which an expression level of the gene encoded by the polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 9 or 35 is lowered.

Group XXXII, claim(s) 37 (in part, as it reads on lowered expression of SEQ ID NOs: 15 and 41), drawn to a transgenic animal model in which an expression level of the gene encoded by the polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 15 or 41 is lowered.

Group XXXIII, claim(s) 37 (in part, as it reads on lowered expression of SEQ ID NOs: 25 and 51), drawn to a transgenic animal model in which an expression level of the gene encoded by the polynucleotide having 65% or more homology or hybridizing to SEQ ID NO: 25 or 51 is lowered.

The inventions listed as Groups I-XXXIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-XXXIII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The first named product is a primary chondrocyte or cultured cell derived from a Runx2/Cbfa1-deficient mouse, which is used in the method of Group I. This technical feature of Group I is shown by Komori et al (Cell, Vol. 89, pages 755-764, May 1997) to lack novelty or inventive step. Komori et al teach primary chondrocytes derived from a Cbfa1-/- mouse (e.g., Figure 5). Therefore the technical feature does not make a contribution over the prior art and does not constitute a special technical feature. Furthermore, the method of Group I is not a method of making or using the polynucleotide sequences of SEQ ID NOs: 1, 3, 5, 9, 15, 25, 27, 29, 31, 35, 41 or 51. A method of screening is not a method of making.

Accordingly, Groups I-XXXIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined

claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Dunston whose telephone number is 571-272-2916. The examiner can normally be reached on M-F, 9 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached at 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Dunston, Ph.D.
Examiner
Art Unit 1636

/JD/

/Celine X Qian Ph.D./
Primary Examiner, Art Unit 1636